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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,449	08/27/2003	Michael L. Robinson	28335/39524A	7321

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/650,449	ROBINSON ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *2-5 and 7-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/19/7*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II in the reply filed on November 13, 2007 is acknowledged.

Claims 2-5 and 7-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 13, 2007.

Claims 1 and 6, in so far as they are directed to a human Hydin polynucleotide (SEQ ID NO: 14) are under examination in the instant office action.

Specification

2. It is noted that Sequence listing filed on January 24, 2008 contains two sequences, SEQ ID NO: 13 and SEQ ID NO: 14, which appear to be duplicates of each other. Clarification of what polynucleotide represented by SEQ ID NO: 13 is required.

Claim Objections

3. Claim 1 is objected to for reciting non-elected subject matter. Appropriate action is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

Claims 1 and 6 encompass a novel isolated nucleic acid molecule of SEQ ID NO: 14, designated human Hydin, Hydrocephalus-associated gene (p. 1 of the instant specification). The instant polynucleotide is a predicted cDNA sequence of a human homolog of a mouse Hydin gene of SEQ ID NO: 1 (p. 9). The invention is based on discovery of "[a] new transgene-induced insertional mutation, OVE459, resulting in autosomal recessive hydrocephalus [...]. This mutation does not complement the spontaneous mutation hy3 and represents a new allele of this gene" (p. 8 of the specification). However, the information presented in the instant specification is limited to the disclosure of the experimental results obtained on transgenic mice with altered genotype within Hydin gene and provides no explanation as how to extrapolate that information to the human polynucleotide sequences, thus, requiring undue experimentation on part of one skilled in the art to research and discover how to use Applicant's invention, as currently claimed.

The factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988).

The nature of the invention is "the identification and characterization of the novel murine Hydin gene and corresponding human homolog sequences. The murine Hydin cDNA sequence is set out as SEQ ID NO: 1 and is 15769 bases and encompasses 87 exons. The murine Hydin gene is located on chromosome 8 and is an allele of the hy3 gene that was previously known in the art. In homozygous hy3/hy3 mice, which spontaneously generate congenital hydrocephalus, there is a frame shift mutation within exon 15 that results in a stop codon. This mutation is believed to be responsible for autosomal recessive congenital hydrocephalus" (pp. 8-9 of the instant specification). The specification further discloses OVE459 mutation within murine Hydin gene and presents experimental data related to OVE459 and *hy3* transgenic mice and analysis of Hydin cDNA, Tables 2 and 3 at pp. 28 and 34-35. The information describing human Hydin polynucleotide is limited to the description of the predicted structure of the nucleic acid sequence, SEQ ID NO: 14, and a statement that, " [t]he present invention contemplates using the human Hydin gene and human Hydin polypeptide in a same or similar manner as described for the mouse Hydin sequences" (p. 44).

The prior art does not recognize that finding specific mutations within murine genes can be directly extrapolated to human homologous sequences. The instant specification provides no factual evidence or a line of scientific reasoning to support a conclusion that experimental results obtained on transgenic mice are predictive of similar findings within human homologous polynucleotide. There appears to be no evidence of record presented in the instant specification that associates the instant polynucleotide of SEQ ID NO: 14 with any disease or disorder, including congenital hydrocephalus.

While the skill level in the art is high, the level of predictability is low. Mutations within polynucleotide sequences by definition represent unpredictable art. The sole working examples in the specification, as originally filed, pertain to the determination of the specific mutation within murine nucleic acid of Hydin gene and correlating the altered genotype of transgenic mice with autosomal recessive congenital hydrocephalus. While it is not necessary that Applicant understands or discloses the mechanism by which the invention functions, in this case, in the absence of such an understanding, no extrapolation can be made of the results obtained from transgenic mice to predicting human mutations of the homologous gene being associated with the similar pathology.

A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to "inventions" consisting of little more than respectable guesses as to the likelihood of their success. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that: "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one

skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one cannot follow the guidance presented therein and use the claimed product without first making a substantial inventive contribution.

Conclusion

5. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

May 5, 2008

/Olga N. Chernyshev, Ph.D./
Primary Examiner, Art Unit 1649